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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,777	09/15/2003	Hassan Ahmad	2551-1-001	1508

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EXAMINER	
MCCORMICK EWOLDT, SUSAN BETH	
ART UNIT	**PAPER NUMBER**
1661	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,777	AHMAD ET AL.	
	Examiner	Art Unit	
	S. B. McCormick-Ewoldt	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-10 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4-10 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The final action dated September 13, 2006 has been withdrawn in favor of the current Office action.

The indicated allowability of claim 2 is withdrawn in view of 112, 1st paragraph rejection below, as well as the newly discovered reference(s) to Türkdoğan *et al.* ("The Role of Antioxidant Vitamins (C and E), Selenium and Nigella Sativa in the Prevention of Liver Fibrosis and Cirrhosis in Rabbits: New Hopes," Dtsch. Tierarztl. Wschr. 108, 71-73, Feb. 2001) and "Botanical- A Modern Herbal: *Anemone hepatica*" (2002). Rejections based on the newly cited reference(s) follow.

Election/Restrictions

Applicant elected Group I and *Nigella sativa*, in the reply filed February 24, 2005.

Claims Pending

Claims 2, 4-10 and 27-29 are pending. Applicant has cancelled claims 1, 3, and 11-26. Claims 2, 4-10 and 27-29 are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using *Actaea rubra*, *Anemone hepatica*, *Anemone nemorosa*, *Nigella sativa*, and *Ranunculus arvensis* in a herbal composition, does not reasonably provide enablement for using only *Nigella sativa* and *Anemone hepatica* in a herbal composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re* Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as

routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is "undue," not "experimentation." " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicted on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case, are discussed below.

The invention is targeted to a pharmaceutical composition for treating a hepatic disorder and/or for increasing the number of immune cells and platelets comprising a therapeutically effective amount of *Nigella sativa* and *Anemone hepatica*, bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. Claims drawn to pharmaceutically acceptable compositions to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments. Thus, claims to a composition may be unbelievable in the absence of strong supporting evidence. It is noted that the instant claims encompasses only two herbals, for example, and yet the instant specification provides no guidance that would permit the skilled artisan to use the invention with only two herbal ingredients.

In the instant case, Applicant has disclosed that the claimed composition contains only two herbal ingredients, *Nigella sativa* and *Anemone hepatica*. The claims specifically disclose two herbal ingredients, *Nigella sativa* and *Anemone hepatica*, while in the specification Applicant shows *Actaea rubra*, *Anemone hepatica*, *Anemone nemorosa*, *Nigella sativa*, and *Ranunculus arvensis* in a herbal composition (see page 9 and 18). Applicant provides no guidance that would permit the skilled artisan to practice the invention commensurate with the *scope* of the instant claims with regard for using two herbal ingredients capable of treating a hepatic disorder and/or for increasing the number of immune cells and platelets. Applicant shows

Actaea rubra, *Anemone hepatica*, *Anemone nemorosa*, *Nigella sativa*, and *Ranunculus arvensis* as the ingredients in an herbal composition

Since there is a working example, one also must consider the guidance provided by the instant specification and the prior art of record. As stated *supra*, the state of the art is unpredictable as it reflects that there is no conclusive evidence that the claimed composition containing only two herbal ingredients, *Nigella sativa* and *Anemone hepatica*, would treat a hepatic disorder and/or for increasing the number of immune cells and platelets.

In re Fisher, 427 F.2D 833, 166 USPQ 18 (CCPA 1970), held that "inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some ways on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; ***however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112***; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (emphasis added).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4-10 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rendered vague and indefinite for the following reason. At lines 3-4, the extract is defined as "a buffered aqueous extract of Anemone hepatica and Nigella sativa,"

However, lines 4-6 recite "wherein the extract of Nigella sativa is present in a concentration of not less than 20% weight per volume". Since claim 2 is defining a singular extract that contains two herbals therein (i.e., Anemone hepatica and Nigella sativa), it is unclear and confusing as to how the extract defined in lines 4-6 is defined as an extract containing only one herbal- i.e. Nigella sativa. (What happened to the Anenome hepatica within the singular extract defined in lines 3-4?)

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph, for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 4-10 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Türkdoğan *et al.* ("The Role of Antioxidant Vitamins (C and E), Selenium and Nigella Sativa in the Prevention of Liver Fibrosis and Cirrhosis in Rabbits: New Hopes," Dtsch. Tierarztl. Wschr. 108, 71-73, Feb. 2001) in view of "Botanical- A Modern Herbal: *Anemone hepatica*" (2002) in further in view of Khan *et al.* ("The *In Vivo* Antifungal Activity of the Aqueous Extract from *Nigella sativa* Seeds," Phytotherapy Research, Vol. 17, pages 183-186 (February 2003)).

Türkdoğan *et al.* ("The Role of Antioxidant Vitamins (C and E), Selenium and Nigella Sativa in the Prevention of Liver Fibrosis and Cirrhosis in Rabbits: New Hopes") teaches that *Nigella sativa* (NS) was used in a study to investigate the role of NS in the prevention of liver fibrosis and cirrhosis and concluded that *Nigella sativa* partly possess antifibrotic and hepatoprotective effects (see summary and page 71, column 2, bottom of 1st paragraph and page 72, column 3, under "Discussion" and page 73, column 1, 1st paragraph).

Türkdoğan *et al.* does not teach wherein *Anemone hepatica* is used in the composition or wherein a buffered aqueous extract is used or where not less than 20% of *Nigella sativa* is used.

"Botanical- A Modern Herbal: *Anemone hepatica*" (2002) teaches that *Anemone hepatica* is used as a mild remedy in disorders of the liver (see top of page 2).

Khan *et al.* ("The *In Vivo* Antifungal Activity of the Aqueous Extract from *Nigella sativa* Seeds") teach a therapeutic composition comprising a buffered aqueous (i.e. phosphate buffered saline) extract of *Nigella sativa* seeds within the claimed concentration range (i.e., above 20% weight per volume). Additionally, Khan teaches that *Nigella sativa* has known hepatoprotective value (page 183, column 2, 1st paragraph).

One of ordinary skill in the art would have used *Nigella sativa* and *Anemone hepatica* together in a composition because the known beneficial hepatoprotective effects of both *Nigella sativa* and *Anemone hepatica*. It was clear from the Türkdoğan reference that *Nigella sativa* (NS) was used to investigate the role of NS in the prevention of liver fibrosis and cirrhosis. It was further clear from "Botanical- A Modern Herbal" that *Anemone hepatica* is used as a mild remedy in disorders of the liver. It was further clear from the Khan reference which teaches a therapeutic composition comprising a buffered aqueous (i.e. phosphate buffered saline) extract of *Nigella sativa* seeds within the claimed concentration range (i.e., above 20% weight per volume) and that *Nigella sativa* has known hepatoprotective properties. Although none of the cited references discloses the type of dosage form, one of skilled in the art would adjust in the conventional working conditions (e.g., incorporating the composition within a commonly employed delivery vehicle routinely used- such as within a table/capsule, suspension, spray, transdermal, suppository; and/or sterilizing such therapeutic composition for standard safety/self-life considerations) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

Therefore, one of ordinary skill in the art would have had a reasonable expectation to combine *Nigella sativa* and *Anemone hepatica* in a composition for the treatment of hepatic disorders as disclosed in the cited references.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiners' supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

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PRIMARY EXAMINER